

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and Therapeutic Systems Research Laboratories, Inc.

Action Requested: Authorization to enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by DRDA while reviewing the Proposal Approval Form that then triggered a review of the project by the OVPR Conflict of Interest Review Committee. A plan for management of the possible risks associated with the conflicts of interest was then developed by the Committee and agreed to by the parties involved.

The proposed research agreement (Agreement) falls under the State of Michigan Conflict of Interest Statute because Dr. Gordon L. Amidon, is both an owner of Therapeutic Systems Research Laboratories (TSRL) and an employee of the University. The law permits such an Agreement provided it is disclosed to the executive officers and approved in advance by a 2/3 vote of the Regents of the University of Michigan (Regents).

Background:

Dr. Gordon L. Amidon is a Professor in the College of Pharmacy and an owner in TSRL. TSRL desires to fund a project in the College of Pharmacy under the direction of Dr. Henry Mosberg, Professor in the College of Pharmacy. Dr. Amidon will not participate in the project in his capacity as an employee of the University.

Nature of the Project:

TSRL has applied for and received a Small Business Innovation Research (SBIR) Program award from the National Institutes of Health for the purpose of enhancing thrombostatin's oral delivery. TSRL wishes to enter into a subcontract with the Regents of the University of Michigan to enable Dr. Mosberg to assist in the performance of this funded research.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is one (1) year and the amount of funding support is \$35,000. Indirect costs are waived on SBIR Phase I awards. The Agreement contains a provision allowing amendment by mutual agreement of the parties. University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

Impact of the Agreement:

The Agreement will support an effort by Dr. Mosberg to develop an orally bioavailable drug for treatment of individuals with acute coronary syndromes (ACS) and also individuals whose cancer is influenced by the mitogenic effects of thrombin.

Recommendation:

This matter has been reviewed and approved by the OVPR Conflict of Interest Review Committee and by the Office of the Dean for the College of Pharmacy. In light of the disclosure made in this document and our finding that the agreement was negotiated in conformance with standard University practices, I recommend that the Board of Regents approve of the University's entering into this Agreement with TSRL.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Stephen Forrest", with a long horizontal flourish extending to the right.

Stephen Forrest  
Vice President for Research

October 2006